JUN 2 4 2014

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 16th September 2013

5.3 Submitter:

Address:	4F-13, No. 79, Sec.1, Hsin Tai Wu Rd., His-Chih Dist., New Taipei City 221, Taiwan
Phone:	+886-2-2698-5678
Fax:	+886-2-2698-9216
Contact:	Crystal Lee (crystal@digio2.com)
Registration number:	3007482861

5.4 Identification of the Device:

Proprietary/ Trade name:	Breeze Nebulizer (NBR-101)
Classification Name:	Nebulizer (Direct Patient Interface)
Device Classification:	II
Regulation Number:	868.5630
Panel:	Anesthesiology
Product Code:	CAF

5.5 Identification of the Predicate Device:

Predicate Device Name:	Micro Air Vibrating Mesh Nebulizer Model - NE-U22
Manufacturer:	Omron Healthcare, Inc.
Product Code:	CAF
510(k) Number:	K062263

5.6 Intended Use and Indications for Use of the subject device.

The Breeze Nebulizer (NBR-101) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (ages 2 years old and above) and adult patients in the home. It is not intended for use with Pentamidine.

5.7 Device Description

Breeze Nebulizer (NBR-101) is a vibrating mesh nebulizer that delivers aerosolized medication to the lower respiratory tract by using a vibrating mesh to create aerosol and provide fine particles to the patient's lungs. It is similar to the predicate device, the FDA-cleared Model NE-U22 Micro Air Vibrating Mesh Nebulizer, cleared under 510(k) K062263. They are identical in purpose, function, core technology and method of operation.

Breeze nebulizer (NBR-101) is a portable size, curvaceous body design that is convenient to hold, and ability to detect the amount of medications available and to turn off automatically. The open button is made of soft materials and gives off an ice blue light, coupled with an overall elegant white exterior.

Breeze Nebulizer (NBR-101) is battery powered, 4 "AAA" and the dimensions is 58(W) X 145(H) X 70(D). The medication container capacity is 8ml maximum and the residual volume is approximately 0.1ml.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the performance of the Breeze Nebulizer.

Testing Item	**Standard and regulations applied**
Electromagnetic Compatibility & Electrical Safety	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (General)
Biocompatibility	ISO 10993-5:2009(E) Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity.

	ISO 10993-10:2002/Amd.1:2006(E) Biological evaluation of medical devices --- Part 10: Tests for irritation and delayed-type hypersensitivity (7.4 Maximization test for delayed hypersensitivity)
	ISO 10993-3:2003/(R)2009, Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity, And Reproductive Toxicity. (Biocompatibility)
	ISO 10993-6:2007/(R)2010, Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation. (Biocompatibility)
	ISO 10993-11:2009, Biological Evaluation Of Medical Devices -- Part 11: Tests For Systemic Toxicity. (Biocompatibility)
	ISO 10993-12:2012, Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials. (Biocompatibility)
Usability	IEC 60601-1-6:2006 Medical electrical equipment –Part 1-6: General requirements for safety –Collateral Standard: Usability.
Performance	EN 13544-1:2007 – Respiratory therapy equipment – Part 1: Nebulizing systems and their components
	EN 13544-2:2002+A1 – Respiratory therapy equipment – Part 2: Tubing and connectors

All the test results demonstrate Breeze Nebulizer (NBR-101) meets the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 EMC and Electrical safety

The performance of the Breeze Nebulizer (NBR-101) is verified and validated according to FDA Guidance Document "Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators", dated October 1, 1993, ANSI/AAMI ES60601-1:2005 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and ANSI/AAMI/IEC 60601-1-2:2007

Medical Electrical Equipment - Pant 1-2: General Requirements for Safety; Electromagnetic Compatibility.

The Breeze Nebulizer (NBR-101) complies with to applicable ANSI/AAMI ES60601-1 and ANSI/AAMI/IEC 60601-1-2 requirements including general requirements, protection against electrical hazards, protection against mechanical hazards, protection against excessive temperatures, hazardous situations and fault conditions, and constructions.

5.11 Substantial Equivalence Determination

The Breeze Nebulizer (NBR-101) has similar intended use, similar fundamental scientific technology, and similar technological characteristics with the predicate device. Information described above can demonstrate the Breeze Nebulizer (NBR-101) is substantial equivalent to the predicate device.

	Proposed Device	Predicate Device
Item	Breeze Nebulizer (NBR-101)	Model Micro Air Vibrating Mesh Nebulizer (NE-U22) (K062263)
Classification	Class II	Class II
Product Code	CAF	CAF
Intended Use	The Breeze Nebulizer (NBR-101) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (ages 2 years old and above) and adult patients in the home. It is not intended for use with Pentamidine.	The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings. It is not intended for use with Pentamidine.
Technology	Vibrating mesh	Vibrating mesh

Environment of Use	Home	Home, Hospital, Sub-acute Institutions
Patient Population	Pediatric (ages 2 years old and above) adult	Pediatric and adult
Nebulizer components cleanable	Yes	Yes
Software driven	Yes	No
Characteristics		
Vibrating Capacity	107kHz	180kHz
Button	ON/OFF Switch	ON/OFF Switch
Reservoir size	8.0ml	7.0ml
Nebulization Rate	0.2~0.4 ml/min	0.25-0.9 ml/min
Environment		
Operation condition	3℃ ~40℃ Max 70% RH	0℃ ~ 45℃ 30% - 85% RH
Storage condition	-10℃ ~ 80℃ Max 70% RH	-25℃ ~ 70℃ 10% - 90% RH
Power		
Power source	Four AAA batteries	Two AA batteries AC adapter AC 120V (60Hz/DC3V)
Power consumption	1.5W	1.5W
Power indicator	LED	LED
Physical		

Dimensions	58mm(W) x 70mm(D) x145mm(H)	38mm(W) x 51mm(D) x 104mm(H)
Weight	123.6 g (without batteries)	97g (without batteries)

5.12 Similarity and differences

The difference between the subject device and predicate device is the proposed device is software driven. The subject device has tested on safety and performance tests and the test results were complied with the test requests. Therefore, the difference of subject device and predicate device didn't raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in design, operation, intended use, method of preparation, and performance claims.

5.13 Conclusion

After analyzing bench tests, testing data, it can be concluded that Breeze Nebulizer (NBR-101) is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 24, 2014

digiO2 International Co., Ltd.
c/o Mr. Michael Lee, President
AcmeBiotechs Co., Ltd.
No.45, Minsheng Rd. Danshui Town
New Taipei City, 251, Taiwan

Re: K133105

Trade/Device Name: Breeze Nebulizer NBR-101
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 20, 2014
Received: May 23, 2014

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Breeze Nebulizer (NBR-101)

Indications for Use:

The Breeze Nebulizer (NBR-101) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (ages 2 years old and above) and adult patients in the home.
It is not intended for use with Pentamidine.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Anya C. Harry -S
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